IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*,	)	
Plaintiffs,	)	
v.	)	
JOSHUA STEIN, *et al.*,	)	Case No. 1:23-cv-00480-CCE-LPA
Defendants,	)	
and	)	
PHILIP E. BERGER, *et al.*,	)	
Intervenor-Defendants.	)	

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

STATEMENT OF THE MATTER

Five months ago, this Court preliminarily enjoined enforcement of two North Carolina abortion restrictions: the Hospitalization Requirement, requiring that abortions after the twelfth week of pregnancy be performed in a hospital,[1] and the IUP Documentation Requirement, requiring that providers document the "existence of an intrauterine pregnancy" before initiating a medication abortion.[2] The Court's opinion

[1] *See* N.C. Gen. Stat. § 90-21.81A (the "Twelve-Week Ban"); *id.* §§ 90-21.81B(3), 90-21.81B(4) (creating rape, incest, and life-limiting anomaly exceptions to the Twelve-Week Ban); *id.* § 90-21.82A(c) (requiring abortions provided after the twelfth week of pregnancy to be performed in a hospital).

[2] *See* N.C. Gen. Stat. § 90-21.83B(a)(7).

detailed the facts supporting its conclusions that Plaintiffs were likely to succeed on the merits of their challenges to both laws. Discovery has decisively confirmed the Court's factual findings.

Abortion procedures are safe—as safe as, and sometimes safer than, equivalent procedures to manage miscarriage. And abortions provided in outpatient clinics are often safer and more affordable than abortions provided in hospitals. As the Court found and the record confirms, there is no health justification for requiring these procedures to be performed in a hospital *only* when provided for the purpose of abortion. DE 80 (PI Order) at 2. And no facts have emerged during discovery contradicting this Court's conclusion that the IUP Documentation Requirement is unconstitutionally vague. *Id*. If permitted to take effect, these laws will undermine both patient safety and the legislature's policy choice to make abortion accessible early in pregnancy and in cases of rape, incest, or "life-limiting" anomaly. Plaintiffs therefore seek summary judgment on all claims.

STATEMENT OF FACTS

I. Abortion in North Carolina

Abortion is a basic component of health care and one of the safest medical treatments in the United States. DE 49-1 (Farris PI Decl.) ¶14; DE 49-2 (Boraas PI Decl.) ¶¶21–22, 32; *accord* DE 64 (AG Stein's Answer) ¶47; DE 55 (DHHS Secretary's Answer) ¶47. Outpatient clinics in North Carolina provide three methods of abortion: medication abortion, aspiration abortion, and dilation and evacuation ("D&E"). DE 49-1 ¶14.

Medication abortion in the first trimester typically involves two medications: mifepristone and misoprostol. DE 49-1 ¶17; DE 49-2 ¶21; DE 55 ¶48; DE 60 (Licensing Board Defendants' Answer) ¶48. The patient first takes mifepristone and then, usually 24 to 48 hours later, takes misoprostol. DE 49-1 ¶17; DE 55 ¶48; DE 60 ¶48. Together, these medications stop the pregnancy's development and cause uterine contractions that expel the uterus's contents, as in a miscarriage. DE 49-1 ¶17; DE 49-2 ¶21; DE 55 ¶48; DE 60 ¶48. Plaintiffs provide this regimen through eleven weeks of pregnancy. DE 49-1 ¶12; DE 42 (Verified First Am. Compl.) ¶49.

For aspiration abortion, the provider passes a small tube, called a cannula, through the patient's vagina and cervix. DE 49-1 ¶21. The cannula is attached to a syringe or electrical pump that creates suction to empty the uterus. DE 49-1 ¶21; DE 49-2 ¶22. Aspiration abortion involves no incisions, cutting, or suturing. DE 49-1 ¶23; DE 49-2 ¶22. In compliance with the Twelve-Week Ban and its exceptions, PPSAT provides aspiration abortion up to approximately fourteen weeks of pregnancy, as measured from the first day of the patient's last menstrual period ("LMP"). Farris Decl. in Supp. of Pls.' Mot. for Summ. J., attached as **Exhibit A**, ¶22.

For D&E, the provider first dilates the patient's cervix using medications and/or physical dilators, then uses a combination of suction and additional instruments to evacuate the uterus. DE 49-1 ¶26; DE 49-2 ¶35. Like aspiration abortion, D&E does not involve any incisions, cutting, or suturing. DE 49-1 ¶28; DE 49-2 ¶22. Abortion providers generally switch from aspiration to D&E around fifteen weeks LMP, depending on the provider's

practice and the patient's individual medical characteristics. *See* Ex. A ¶26; DE 74-1 (Boraas Dep.), 58:5–59:4, 151:17–23.

For aspiration and D&E procedures, PPSAT uses local, mild, or moderate sedation, but not deep sedation or general anesthesia. DE 49-1 ¶¶22, 26, 72; DE 74-2 (Farris Dep.) 88:9–25.

While abortion is very safe, abortion remains politically stigmatized in North Carolina. Ex. A ¶76. People seeking abortions, and the medical staff who care for them, face unique and routine prejudice and harassment, which is not the case for any other medical care. *Id.* ¶¶76–77. Abortion providers risk professional retaliation, harassment, and physical violence. *Id.* ¶¶79–82. And though abortion providers in North Carolina are highly trained and provide evidence-based, patient-centered medical care, they face baseless stereotypes that they lack skill and do not care about patient safety. *Id.* ¶78; *e.g.* DE 74-11 (*Chemical Abortion: Protocols for a Risky Business*) at 2–3 (lobbying materials referring to "the negligent and profit-seeking abortion drug industry").

II. The Hospitalization Requirement Does Not Make Abortion Safer Than It Already Is.

Both medication and procedural abortions can be safely provided in a clinic. DE 49-1 ¶¶14–15, 36, 44; DE 49-2 ¶32; *accord* DE 64 ¶47. PPSAT safely provided abortions in its licensed clinics past the twelfth week of pregnancy for more than fifteen years before the Twelve-Week Ban took effect. DE 49-1 ¶12; *accord* DE 64 ¶¶38, 76.

In fact, because abortion safety is generally a function of the abortion provider's experience rather than the clinical setting, D&Es can be *safer* in outpatient clinics than in hospitals. DE 80 at 26 & n.15; Ex. A ¶43 & n.35; *see also* DE 74-3 (1st Wubbenhorst Dep.) 131:22–132:1 (Intervenors' witness acknowledging research supporting this fact). And abortions at outpatient clinics are often more affordable, easier to navigate, and less time-consuming for patients than abortions at hospitals. DE 80 at 26; Ex. A ¶41; DE 49-2 ¶38. Abortions in cases of rape, incest, or "life-limiting" anomaly are usually technically identical to abortions sought for other reasons, and thus can be provided safely in clinics. Ex. A ¶57; Wheeler Dep., attached as **Exhibit C**, 110:20–111:6, 114:17–21, 184:17–20. Indeed, hospital providers in North Carolina refer patients with "life-limiting" anomalies to PPSAT for abortions. Ex. A ¶8.

While the risks associated with abortion increase as gestation progresses, abortion remains very safe throughout pregnancy. DE 80 at 24; Ex. A ¶93; Boraas Decl. in Supp. of Pls.' Mot. for Summ. J., attached as **Exhibit B** ¶28. Complications from abortion are rare. Ex. A ¶47; *accord* DE 64 ¶47. PPSAT performed 43,339 abortions in North Carolina between January 1, 2020 and December 31, 2023; 596 complications resulted, most of which were minor, such as ongoing pregnancy (201 cases), retained tissue (210 cases), or pain/bleeding less than hemorrhage (105 cases). Ex A. ¶51; *id*. Ex. 3 (Bates 0146).

The vast majority of abortion complications are treated in outpatient facilities. Ex. A ¶47; *accord* DE 64 ¶47. For example, hemorrhage, uterine infection, cervical laceration,

and uterine perforation can all be treated in a clinic. *See* Ex. A ¶¶46–51; DE 74-1, 170:17–173:7; *accord* DE 74-4 (1st Bane Dep.) 94:18–95:1, 104:20–23.

Research demonstrates that major abortion complications, defined as those requiring hospital admission, surgery, or blood transfusion, occur in just 0.23% of abortions. Ex. A ¶32; *accord* DE 64 ¶¶53, 69; DE 55 ¶¶53, 69. PPSAT has relationships with hospitals near its clinics and emergency management protocols in the rare event that hospital transfer is needed. Ex. A ¶53. Of the 43,339 abortions PPSAT provided from 2020–2023, just 34 (0.078%) resulted in complications requiring hospital transfer. *Id*. All patients were treated and released in stable condition, and only 7 of the 34 were admitted. *Id*.

III. The Hospitalization Requirement Uniquely Burdens Abortion Without Medical Justification.

There is no medical reason to mandate that abortions occur in a hospital, while permitting the same procedures to be performed in clinics for miscarriage management. Ex. B ¶¶18, 20.

"Miscarriage" is when a pregnancy is ending on its own. If the person's body does not expel the pregnancy, medical treatment, known as "miscarriage management," is needed to empty the uterus. *See* Ex. A ¶¶18, 25, 29; Ex. B ¶17 n.6. Aspiration and D&E are used for both abortion and miscarriage management. Ex. A ¶¶25, 29; Ex. B ¶¶18, 20; *see* DE 64 ¶73; DE 74-4, 28:12–17, 29:18–20; DE 74-3, 114:19–21; Ex. C, 151:10–22.

It is undisputed that every complication that could result from aspiration or D&E

for induced abortion could *also* result from those same procedures for miscarriage management. Tr. of Prelim. Inj. Proceedings, attached as **Exhibit F**, 120:20–121:5; Ex. A ¶¶25, 29; Ex. C, 147:10-21, 153:1-16, 153:23-25, 154:12–155:14. Complication rates are *higher* for miscarriage than for abortion. Ex. A ¶37 & n.28. And D&E for miscarriage management carries a higher risk of disseminated intravascular coagulopathy ("DIC"), a dangerous clotting disorder, than D&E for induced abortion. *Id.* ¶29 & n.12; *see also* 2nd Bane Dep., attached as **Exhibit D,** 64:16–20.

Although abortion is less risky than miscarriage management, North Carolina requires hospitalization for abortion—but not miscarriage management—after the twelfth week of pregnancy. N.C. Gen. Stat. § 90-21.81(9b)(c) (excluding removal of dead embryo or fetus from definition of "surgical abortion" and, thus, from hospitalization requirement); *see* DE 64 ¶73.

Procedural abortions are similar in technique and risk to certain outpatient diagnostic gynecology procedures. DE 49-1 ¶¶24, 28, 36–44. And abortion is safer than other procedures routinely performed outside of hospital settings, including vasectomies, colonoscopies, and tonsillectomies. DE 49-1 ¶32; DE 64 ¶74.

Complications from term pregnancy and childbirth are far more common than abortion-related complications. Ex. A ¶34; DE 74-1, 92:3–10, 173:8–175:5; *see also* DE 74-4, 94:4–13; 100:5–16; 101:16–23; 103:17–21. The mortality rate for childbirth is approximately 12 to 14 times greater than the rate for abortion. Ex. A ¶35; *accord* DE 64 ¶70; DE 55 ¶70. Yet North Carolina does not require childbirth to occur in a hospital. N.C.

Gen. Stat. § 90-178.4 (as amended by S.B. 20, § 4.3(d), effective Oct. 1, 2023) (providing for "planned birth outside of a hospital setting").

IV. The IUP Documentation Requirement

North Carolina requires an ultrasound prior to every abortion. 10A N.C. Admin. Code 14E.0305(d), *replaced by* 10A N.C. Admin. Code 14E.0321(d) (effective July 18, 2023). Before the fifth or sixth week of pregnancy, pregnancy tissue may not be visible even by transvaginal ultrasound. DE 80 at 15; Ex. B ¶43; DE 49-1 ¶49. Patients in this situation are categorized as having pregnancies of unknown location. DE 49-1 ¶9.

Using evidence-based practices, PPSAT screens these patients for risk of ectopic pregnancy—a pregnancy that has implanted outside the uterus—by asking questions about their menstrual history, pregnancy history, contraceptive history, and current symptoms. Ex. A ¶63 & n.48. If PPSAT determines that the patient is at elevated risk of ectopic pregnancy, the patient is immediately referred to another provider, typically an emergency department, for diagnosis and treatment. *Id*.

Otherwise, PPSAT offers three options: medication abortion; aspiration abortion; or a follow-up appointment when the pregnancy may be visible by ultrasound. *Id*. ¶64; DE 74-2, 163:18–164:8. If a low-risk patient chooses medication abortion, PPSAT simultaneously provides the medication abortion and conducts testing to rule out ectopic pregnancy: serial blood draws to test the levels of the pregnancy hormone human chorionic gonadotropin ("hCG"); repeat ultrasounds where feasible; and close follow-up by a clinician. Ex. A ¶¶65–68; DE 74-2, 164:9–24. All patients are educated on signs and

symptoms of both medication abortion and ectopic rupture, and are warned both verbally and in writing of the dangers of untreated ectopic pregnancy. Ex. A ¶72; DE 74-15 (PPSAT Patient Education Materials). If this concurrent testing or post-abortion symptoms suggest possible ectopic pregnancy, PPSAT further evaluates the patient and refers them to an emergency department when indicated, even if the patient has already taken the abortion medications. Ex. A ¶¶66–68.

PPSAT's protocol is evidence-based and has been found to be safe and effective. *See* DE 49-2 ¶¶44–47. It does not delay detection of ectopic pregnancy, and one study concluded that this protocol leads to *earlier* exclusion of ectopic pregnancy than waiting until an intrauterine pregnancy can be seen by ultrasound. *Id.* ¶46 & n.23; DE 69-1 (Boraas PI Reply Decl.) ¶49 & n.61; Ex. A ¶69 & n.50.

Medication abortion does not make ectopic pregnancy more dangerous. DE 80 at 14–15; Ex. A ¶71; DE 69-2 (Farris PI Reply Decl.) ¶11. Rather, medication abortion is contraindicated for patients with confirmed or suspected ectopic pregnancies because it does not treat ectopic pregnancy. DE 80 at 13; Ex. A ¶71; DE 69-1 ¶50; DE 74-2, 155:11–14; DE 74-3, 143:19–21. Mifepristone is not contraindicated where ectopic pregnancy is not suspected. *See* DE 65-2 (FDA Mifeprex Label) at 4; *see also* DE 74-2, 102:22–103:6, 108:2–7, 110:10–19, 162:3–14, 168:17–23; DE 74-1, 127:6–16, 145:20–146:1.

It is undisputed that the IUP Documentation Requirement itself does not require evaluation or treatment for ectopic pregnancy. Ex. A ¶70; *accord* DE (Intervenors' PI Opp.) 65 at 24; Ex. C, 233:20–234:8; 2nd Wubbenhorst Dep., attached as **Exhibit E**,

61:22–25; Ex. F, 87:21–88:6. And if a patient with a pregnancy of unknown location were referred to a hospital for evaluation instead of receiving a medication abortion, the hospital would generally perform the very same serial blood testing that Plaintiffs perform *simultaneously* with the medication abortion. DE 49-1 ¶59; DE 49-2 ¶48; *see also* DE 74-4, 117:22–118:25. Referring a patient for evaluation instead of providing a medication abortion therefore does not lead to earlier or more accurate diagnosis of ectopic pregnancy. DE 49-1 ¶59; DE 49-2 ¶50. Instead, it just delays the patient's abortion. DE 49-1 ¶59; DE 49-2 ¶48; *see* DE 55 ¶15.

QUESTIONS PRESENTED

Have Plaintiffs demonstrated that there is no genuine dispute as to any material fact and that they are entitled to summary judgment on their claims that:

1. The Hospitalization Requirement violates the Equal Protection Clause?
2. The IUP Documentation Requirement violates the Due Process Clause?

ARGUMENT

I. Legal Standard

Summary judgment is proper where "there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." *Design Res., Inc. v. Leather Indus. of Am.*, 789 F.3d 495, 500 (4th Cir. 2015) (citing Fed. R. Civ. P. 56(a)). While courts must draw all reasonable inferences in the light most favorable to the nonmoving party, the nonmovant bears the burden of demonstrating that a dispute of *material* fact exists.

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). The nonmovant "must provide more than a scintilla of evidence—and not merely conclusory allegations or speculation—upon which a jury could properly find in its favor." *Design Res., Inc*., 789 F.3d at 500 (citation omitted) (quoting *CoreTel Va., LLC v. Verizon Va., LLC*, 752 F.3d 364, 370 (4th Cir. 2014)).

II. The Hospitalization Requirement Irrationally Distinguishes Between Abortion and Miscarriage Management.

The Hospitalization Requirement violates the Equal Protection Clause of the Fourteenth Amendment because—as this Court already found and as the full record confirms—its distinction between abortion and miscarriage management is not rationally related to North Carolina's asserted interest in patient safety.[3] No evidence supports subjecting patients seeking abortion to the increased expense, logistical burden, and even heightened risk of a hospital setting, while exempting patients seeking the *very same procedures* for a different purpose.[4]

Although rational basis is a deferential standard, it is not "toothless." *See, e.g.*, *Matthews v. Lucas*, 427 U.S. 495, 510 (1976); *St. Joseph Abbey v. Castille*, 712 F.3d 215, 223 (5th Cir. 2013) ("[P]laintiffs may . . . negate a seemingly plausible basis for the law by adducing evidence of irrationality."). Legislative classifications "must rest upon some ground of difference having a fair and substantial relation to the object of the legislation."

[3] *See* Ex. F, 98:6–16; DE 65 (Intervenors' PI Opp.) at 2, 8; DE 49 at 11.
[4] N.C. Gen. Stat. § 90-21.81(9b)(c).

Eisenstadt v. Baird, 405 U.S. 438, 447 (1972). Comparators need not be alike in every way; rather, rational basis review asks whether there are differences between them that relate to the purpose of the challenged law. *Catherine H. Barber Mem'l Shelter, Inc. v. Town of N. Wilkesboro Bd. of Adjustment of Town of N. Wilkesboro*, 576 F. Supp. 3d 318, 338 (W.D.N.C. 2021) (granting summary judgment to plaintiff under rational basis review).

It remains undisputed that aspiration and D&E procedures after the twelfth week of pregnancy are performed with the same clinical techniques and carry the same risks whether performed for abortion or miscarriage management. DE 80 at 23–24, 31–32; Ex. A ¶46; Ex. F, 121:3–5 (undisputed that the same types of complications may arise from abortion and miscarriage management); *see also, e.g.*, Ex. C, 147:15–21 (Intervenors' witness explaining D&E for miscarriage management can cause trauma to the endometrial cavity and cervix); 153:1–3 (same for hemorrhage); 153:23–155:14 (same for infection, cervical laceration, retained products of conception, uterine perforation, abnormal placentation, and embolism). Indeed, as the Court found, when used for abortion these procedures are just as safe as—and can be *safer* than—the same procedures when used for miscarriage management. DE 80 at 24, 26; *supra* Facts, Part III. Intervenors' experts could not identify any research to the contrary. Ex. C, 185:7–13; Ex. D, 55:25–56:8.

Abortion and miscarriage management after the twelfth week of pregnancy are thus similarly situated for purposes of patient safety. DE 80 at 29–30; *Eisenstadt*, 405 U.S. at 450–52. The Hospitalization Requirement treats the same procedures differently "based on the reason the patient needs or wants the procedure, not based on any medical difference

between the procedures or on differing risks." DE 80 at 30. This classification is "so attenuated" from patient safety "as to render the distinction arbitrary or irrational." *City of Cleburne, Tex. v. Cleburne Living Ctr.*, 473 U.S. 432, 446 (1985).

Moreover, it is not rational to require *all abortion patients* to be hospitalized simply because an exceedingly small number may experience a complication requiring hospitalization. DE 69-2 ¶8; DE 69-1 ¶¶30–34; *O'Day v. George Arakelian Farms, Inc.*, 536 F.2d 856, 860 (9th Cir. 1976) (finding a law irrational where it was "grossly excessive" in relation to government interest). Complications from aspiration and D&E abortions are rare, and can almost always be safely managed in an outpatient clinic. Ex. A ¶¶32–33, 47, 53 (outlining PPSAT transfer protocols and exceptionally low percentage (0.078%) of patients needing transfer from 2020–2023, all of whom were treated and released in stable condition, with only 7 out of 43,339 abortions (0.016%) requiring hospital admission); *see* Ex. B, ¶22. Because hospitalization is not required for miscarriage management, or for riskier procedures like vasectomies or colonoscopies, *supra* Facts, Part III, here "the state seems indifferent to complications from non-hospital procedures other than surgical abortion (especially other gynecological procedures), even when they are more likely to produce complications." *Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 790 (7th Cir. 2013); DE 80 at 29–30.

The Hospitalization Requirement is especially irrational because it applies only to survivors of rape or incest and patients with grave fetal diagnoses. N.C. Gen. Stat. §§ 90-21.81B(3), 90-21.81B(4). The legislature made a policy decision to protect access to

abortion in these circumstances. But the Hospitalization Requirement reduces the number of providers available to these patients, especially if they have lower incomes or live in rural areas. Ex. A ¶¶ 83, 89–93; *accord* DE 55 ¶16; *Hooper v. Bernalillo Cnty. Assessor*, 472 U.S. 612, 619–23 (1985) (finding no rational basis for legislative classification that ran contrary to government's purported goals). The Hospitalization Requirement therefore makes accessing abortion even more challenging for people already facing hardships due to the circumstances of their pregnancies.

And it does so without any medical justification. A pregnancy resulting from rape or incest does not increase the patient's medical risk, and there is no difference in the technical performance of a D&E in these circumstances. Ex. C, 110:20–111:6; 184:17–20. Similarly, "life-limiting" anomalies usually do not make pregnancy riskier or change how a procedural abortion is performed. Ex. A ¶57; Ex. C, 114:17–21, 184:5–7. There is therefore no safety reason to require abortions in these circumstances to be provided in a hospital. Indeed, PPSAT has received referrals from North Carolina hospitals for patients seeking abortion after the twelfth week of pregnancy due to a "life-limiting" anomaly. Ex. A ¶57.

Licensed abortion clinics offer particular benefits over hospitals. PPSAT physicians and staff are trained to provide trauma-informed care and equipped to work with law enforcement if a patient desires. Ex. A ¶¶95–96. At a licensed abortion clinic, patients can trust that their care team—from the front desk staff to the physician performing their procedure—will respect their reproductive decisionmaking. DE 49-1 ¶76; DE 49-2 ¶37.

While there are excellent physicians and staff providing compassionate, patient-centered care in hospital settings, abortion is a uniquely stigmatized procedure, and patients are *more likely* to encounter judgment and providers who refuse to participate in abortions[5] at a hospital than at a licensed abortion clinic in North Carolina. DE 49-1 ¶76; DE 49-2 ¶37.

Far from advancing North Carolina's interest in patient health and safety, the Hospitalization Requirement would harm patients. *See Hooper*, 472 U.S. at 619–23. Patients may be more likely to encounter an inexperienced abortion provider at a North Carolina hospital, increasing the risk of the abortion procedure relative to one provided by an experienced provider in a specialized clinic setting. Ex. A ¶¶43, 94. Hospital abortions can be prohibitively expensive, and even patients who can ultimately afford them may be delayed by the need to seek additional funds. DE 80 at 32; Ex. A ¶90. In turn, any delay increases the patient's medical risk, because while abortion is very safe, it is undisputed that its risks increase with gestational age. DE 80 at 25; Ex. A ¶93; Ex. B ¶28; Ex. F, 72:11–16.

The Hospitalization Requirement is therefore not rationally related to a purported government interest in patient safety. *See Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. Dep't of Health*, 64 F. Supp. 3d 1235, 1257 (S.D. Ind. 2014).

Absent a health-related justification, the only remaining purpose for the Hospitalization Requirement is a "bare desire to harm" people who seek or provide

[5] *See, e.g.*, N.C. Gen. Stat. § 90-21.81C(e), -(f).

abortion, which is not a legitimate state interest. *Cleburne Living Ctr.*, 473 U.S. at 447, 448, 450 (reasoning, after ruling out other purported justifications, that only impermissible animus towards persons with intellectual disabilities could have motivated the challenged regulation); *U.S. Dep't of Agric. v. Moreno*, 413 U.S. 528, 534 (1973); *Romer v. Evans*, 517 U.S. 620, 632 (1996) (requiring a rational relationship to a legitimate legislative end "ensure[s] that classifications are not drawn for the purpose of disadvantaging the group burdened by the law"). Abortion is not "so special a case that all other professional rights and medical norms go out the window." *Stuart v. Camnitz*, 774 F.3d 238, 255–56 (4th Cir. 2014).

Because the Hospitalization Requirement is not rationally related to a legitimate government interest, it fails rational basis review, and Plaintiffs should be granted summary judgment.

III. The IUP Documentation Requirement Is Unconstitutionally Vague.

To survive Plaintiffs' vagueness challenge, the IUP Documentation Requirement must "include sufficient standards to prevent arbitrary and discriminatory enforcement" and "give a person of ordinary intelligence adequate notice of what conduct is prohibited." *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 272 (4th Cir. 2019) (en banc); *see also Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018); *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). As this Court has already held, DE 80 at 18, the IUP Documentation Requirement does neither, and no evidence has emerged that would change this Court's preliminary determination.

As the Court noted, "providers cannot be sure whether they are facing only civil and quasi-criminal penalties" or "criminal sanctions" for violating the IUP Documentation Requirement. *Id*. Intervenors have taken inconsistent positions, arguing in briefing that the Act *does* impose criminal penalties, while stating at oral argument that the Act imposes *only civil* penalties. *Compare, e.g.*, DE 65 at 18, *with* DE 80 at 21; Ex. F, 95:9–19. Abortion "[p]roviders are entitled to 'reasonable notice' of whether they can be criminally prosecuted for violating this provision." DE 80 at 21 (citing *Johnson v. U.S.*, 576 U.S. 591, 596 (2015)). Failing to provide such notice makes the law impermissibly vague. *See Bittner v. U.S.*, 598 U.S. 85, 102 (2023) (noting the "Due Process Clause's promise that 'a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed'" (citing *McBoyle v. U.S.*, 283 U.S. 25, 27 (1931))).

Moreover, laws with criminal penalties demand a "stricter standard" of review for vagueness than laws that impose purely civil punishments. *See Manning*, 930 F.3d at 272–73; *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests. Inc.*, 455 U.S. 489, 498 (1982). Even "laws that nominally impose only civil consequences warrant a 'relatively strict test' for vagueness if the law is 'quasi-criminal' and has a stigmatizing effect," *Manning*, 930 F.3d at 272–73, by, for example, imposing "significant civil and administrative penalties, including fines and license revocation," *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 422 (5th Cir. 2001). Because the Act unquestionably contains quasi-criminal

penalties—and because criminal penalties are "likely," DE 80 at 20–21[6]—this Court correctly determined that, "whether applying the strict standard required when criminal prosecution is a possibility or the relatively strict standard when quasi-criminal sanctions are possible, the IUP requirement in the Act is unconstitutionally vague." *Id.* at 21.

Because discovery has produced nothing that would alter this conclusion, the Court's initial reasoning still applies. The IUP Documentation Requirement is vague because it fails to make clear what an abortion provider must *actually do*. The Act provides that, prior to providing a medication abortion, "[a] physician . . . shall . . . [d]ocument in the woman's medical chart the probable gestational age and existence of an intrauterine pregnancy." N.C. Gen. Stat. § 90-21.83B(a)(7). The Attorney General and Intervenors interpret this provision differently, underscoring its vagueness. The Attorney General has argued "that the provider must only determine that there is a 'probable existence of an intrauterine pregnancy.'" DE 80 at 19. But as this Court noted, even if the IUP Documentation Requirement were construed as the Attorney General suggests, it would remain unclear how certain the provider's determination must be. DE 80 at 19, 22. PPSAT screens patients with pregnancies of unknown location for risk of ectopic pregnancy, and only low-risk patients are offered medication abortion. Ex. A ¶¶63–65. But the law does

[6] The North Carolina Medical Board may discipline physicians who violate the Act. N.C. Gen. Stat. § 90-21.88A. Physicians who perform an abortion in knowing or reckless violation of the Act are subject to civil actions for damages and fees. *Id.* §§ 90-21.88(a), -(c). Additionally, providing an abortion that does not fit within the exceptions to the Twelve-Week Ban is a felony offense. *Id.* §§ 90-21.81A, 90-21.81B; *see also id.* §§ 14-44, -45, -23.7(1).

not indicate whether this safe, evidence-based protocol is legally sufficient to satisfy the IUP Documentation Requirement. And Intervenors have claimed that the provider must be *certain* the pregnancy is intrauterine and must "rule out" ectopic pregnancy to proceed with medication abortion. DE 80 at 19. Thus, although the Attorney General's "interpretation seems more likely," *id*., the IUP Documentation Requirement nevertheless "specifies no standard of conduct," thereby leaving "uncertainty about . . . what specific conduct is covered by the statute and what is not." *Manning*, 930 F.3d at 274–75, 278.

The IUP Documentation Requirement thus lacks *any* standards that might guide a physician—or the law's enforcers—in determining that an intrauterine pregnancy is "probable," let alone the "explicit standards" that are constitutionally required to avert vague criminal and quasi-criminal laws. *See Grayned*, 408 U.S. at 107–08. Plaintiffs still face a regulatory "trap" and lack "fair warning" of what is proscribed and what is permitted. This all but invites "arbitrary and discriminatory enforcement," *even if* the Attorney General's reading of the requirement is correct. *See* DE 80 at 17, 20 ("The Act itself provides no standards for how certain the provider must be before documenting the probable existence of an intrauterine pregnancy."); Ex. F, 116:9–17 (counsel for the Attorney General explaining that vague laws hamper law enforcement).

Additionally, the IUP Documentation Requirement is vague because, to the extent it bans medication abortion in the earliest weeks of pregnancy, it directly contradicts another provision of the Act, which provides that "it *shall not be unlawful* to procure or cause a miscarriage or an abortion in the State of North Carolina . . . [d]uring the first 12

weeks of a woman's pregnancy *when a medical abortion is procured*." N.C. Gen. Stat. § 90-21.81B(2) (emphasis added). As this Court observed, this contradiction "enhance[s]" the "vagueness problem" of the statute, creating a situation in which "[p]roviders cannot know if medical abortion is authorized at any point through the twelfth week, as the statute explicitly says, or if the procedure is implicitly banned in early pregnancy." DE 80 at 20. To the extent the IUP Documentation Requirement prohibits the earliest medication abortions, its direct conflict with another provision of the same Act leaves "a person of ordinary intelligence" without "adequate notice of what conduct is prohibited." *Manning*, 930 F.3d at 272; *Raley v. Ohio*, 360 U.S. 423, 438 (1959).

As a matter of law, the IUP Documentation requirement is unconstitutionally vague. Accordingly, Plaintiffs are entitled to summary judgment on this claim.

IV. If the IUP Documentation Requirement Bans Early Medication Abortion, It Is Irrational.

If the Court concludes that the IUP Documentation Requirement is not vague and instead requires PPSAT to document that an intrauterine pregnancy is visible by ultrasound before providing a medication abortion, it is undisputed that the Requirement would ban medication abortion in the first five or six weeks of pregnancy. DE 80 at 15. So interpreted, the IUP Documentation Requirement violates the Due Process Clause because it has no rational relationship to patient safety. *See Doe v. Settle*, 24 F.4th 932, 943–44, 953 (4th Cir. 2022) ("A substantive due process challenge is considered under rational-basis review unless some fundamental right is implicated."); *Romer*, 517 U.S. at 635 (holding that a law

is irrational if its requirements are "so far removed from [its] particular justifications that . . . it [is] impossible to credit them"). First, it prohibits patients from obtaining abortions at the point in pregnancy when abortion is safest. Second, it does nothing to facilitate prompt screening and treatment for ectopic pregnancy, despite Intervenors' suggestion that this is its purpose. Instead, it only delays patients' access to urgently desired medical care by proscribing what this Court deemed an "established," evidence-based protocol for "safely administering medical abortion before the pregnancy can be seen on an ultrasound but where screening about the patient's medical history and symptoms permit a physician to determine that an ectopic is unlikely." DE 80 at 19.

It is undisputed that abortion is safest earlier in pregnancy. *See, e.g.*, Ex. A ¶93; *accord* Ex. F, 72:11–16; DE 74-3, 64:14–65:5; DE 65-1 (Wubbenhorst PI Decl.) ¶38; DE 65-3 (Bane PI Decl.) ¶35. Indeed, the Act's express authorization of medication abortion through the twelfth week of pregnancy indicates the legislature's policy preference that abortions occur early in pregnancy. *See* N.C. Gen. Stat. § 90-21.81B(2). Intervenors' interpretation of the IUP Documentation Requirement, however, would *prohibit* a medication abortion during the earliest weeks of pregnancy. And Intervenors concede that it will force some patients to obtain medication abortions later in pregnancy, *see* DE 75 (Intervenors' Supp. Br.) at 10, when the medical risks have increased, DE 65 at 3.

Intervenors instead claim that it is unsafe to provide medication abortion until an ectopic pregnancy has been definitively ruled out. *See, e.g.*, Ex. E, 58:10–14; DE 74-4, 142:24–143:14. The FDA's mifepristone label is Intervenors' "primary evidence" on this

point. *See* Ex. F, 91:6–20, 117:13–17. Although the FDA label indicates that mifepristone is "contraindicated" for "confirmed or suspected ectopic pregnancy," that is because mifepristone "is not effective for terminating ectopic pregnancies." DE 65-2 at 4. It is undisputed that mifepristone does not increase the likelihood of a negative outcome from an ectopic pregnancy. *See, e.g.*, Ex. F, 88:7–15; DE 74-3, 143:15–18.

Moreover, PPSAT *does not provide* medication abortion to patients with "confirmed or suspected" ectopic pregnancies. Rather, PPSAT's protocol is designed to ensure that medication abortion is administered only to patients with pregnancies of unknown location who are at low risk of ectopic pregnancy. *See* Ex. A ¶¶62–63. Mifepristone is not contraindicated for pregnancies of unknown location, where ectopic pregnancy is neither "confirmed" nor "suspected." *See, e.g.*, Ex. C, 220:9–11; DE 74-4, 109:12–14. And there is no material disagreement that a pregnancy of unknown location, without additional ectopic pregnancy risk factors, is not equivalent to a confirmed or suspected ectopic pregnancy. *See* Ex. C, 222:1–16; Ex. E, 54:4–24 (stating that "ectopic pregnancy should be suspected" when a patient has a pregnancy of unknown location *and* additional clinical findings are present). As one of Intervenors' witnesses conceded, pregnancies should not be assumed to be ectopic until proven otherwise. Ex. C, 220:24–221:1.

Further, as this Court recognized, the FDA label provides that "the medication can safely be administered *even if* an ectopic pregnancy cannot be definitively ruled out, so long as the patient is appropriately monitored." DE 80 at 20 (emphasis added) (citing DE 65-2 at 7). At PPSAT, patients with a pregnancy of unknown location are educated

specifically about ectopic pregnancy's risks and symptoms and are closely monitored after receiving a medication abortion. Ex. A ¶¶63–66, 72; DE 74-15. Because PPSAT's protocol ensures that such patients are "appropriately monitored," medication abortion "can safely be administered," even if it is too early to see an intrauterine pregnancy on ultrasound. DE 80 at 16, 19, 20. Intervenors have not identified a single patient who suffered a negative outcome as a result of PPSAT's protocol. *See, e.g.*, DE 74-3, 153:18–21.

It is undisputed that PPSAT's protocol for pregnancies of unknown location does not delay detection of ectopic pregnancy, and can even lead to *earlier* exclusion of ectopic pregnancy than waiting to see if an intrauterine pregnancy can be detected later. Ex. A ¶ 69 & n.50; *accord* Ex. D, 35:24–36:16. By contrast, and as Intervenors agree, nothing in the IUP Documentation Requirement requires patients with pregnancy of unknown location to receive *any* further screening for ectopic pregnancy. *See* DE 80 at 16; DE 65 at 24 ("The IUP documentation requirement neither commands nor prevents a physician from 'referring a patient for ectopic evaluation.'"); Ex. E, 61:22–25; Ex. F, 87:21–88:6. Thus, if Intervenors' purported justification for the IUP Documentation Requirement is the prompt diagnosis of ectopic pregnancy, it (as interpreted by Intervenors) is plainly irrational because it makes such a prompt diagnosis *less* likely. *Cf. Van Hollen*, 738 F.3d at 790 (finding irrationality where abortion restriction evinced "indifferen[ce]" to unregulated gynecological procedures "even when they are more likely to produce complications").

Because it is undisputed that the IUP Documentation Requirement delays patients seeking medication abortion and does nothing to identify or treat ectopic pregnancy,

undermining both patient safety and the legislature's own policy aims, Plaintiffs are entitled to summary judgment on their claim that it violates the Due Process Clause.

V. This Court Should Grant Declaratory and Permanent Injunctive Relief.

The Court should declare that the Hospitalization Requirement violates the Equal Protection Clause and that the IUP Documentation Requirement violates the Due Process Clause. Plaintiffs have demonstrated an "actual controversy," which is synonymous with Article III's case and controversy requirement. *See* DE 80 at 7–10; *Volvo Constr. Equip. N. Am., Inc. v. CLM Equip. Co., Inc.*, 386 F.3d 581, 592–93 (4th Cir. 2004) (describing criteria for declaratory relief). This Court has independent jurisdiction over Plaintiffs' claims under 28 U.S.C. §§ 1331 and 1343(a). And declaratory relief "will serve a useful purpose in clarifying and settling the legal relations in issue." *Volvo Constr. Equip.*, 386 F.3d at 594 (internal quotations omitted).

Permanent injunctive relief against both restrictions is also warranted because enforcement will irreparably harm Plaintiffs and their patients. Ex. A ¶¶8–10, 83–103. Further, the loss of constitutional freedoms unquestionably constitutes irreparable injury, *see Elrod v. Burns*, 427 U.S. 347, 373–74 (1976) (plurality opinion), and monetary damages would be inadequate to compensate for these constitutional harms, *Legend Night Club v. Miller*, 637 F.3d 291, 302–03 (4th Cir. 2011). Defendants and Intervenors will not be harmed by the issuance of an injunction that prevents enforcement of an unconstitutional restriction, *id.*; *Centro Tepeyac v. Montgomery Cnty.*, 722 F.3d 184, 191 (4th Cir. 2013), and upholding constitutional rights serves the public interest, *Newsom ex rel. Newsom v.*

Albemarle Cnty. Sch. Bd., 354 F.3d 249, 261 (4th Cir. 2003).

CONCLUSION

For these reasons, Plaintiffs respectfully request that this Court grant Plaintiffs' motion for summary judgment, declare the Hospitalization Requirement and IUP Documentation Requirement unconstitutional, and enter an order permanently enjoining enforcement of these restrictions.

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Respectfully submitted,

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CERTIFICATE OF WORD COUNT

Relying on the word count function of Microsoft Word, I hereby certify that this brief is 6,243 words in length and, therefore, complies with the 6,250 word limitation prescribed by Local Rule 56.1(c) and the Court's text order of October 24, 2023, adopting the parties' Amended Joint Rule 26(f) Report.

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CERTIFICATE OF SERVICE

I hereby certify that, on March 1, 2024, I electronically filed the foregoing with the clerk of the court by using the CM/ECF system, which served notice of this electronic filing to all counsel of record.

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